



National Stroke Association

*Dedicated to reducing
the incidence and
impact of stroke*

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National
Stroke
Association

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To Whom It May Concern:

The National Stroke Association (NSA) supports the Citizen Petition (Docket #2005P-0048/CP1) recently filed by McNeil Consumer & Specialty Pharmaceuticals that requests a change to the professional labeling for aspirin dosing to specify the more favorable benefit/risk profile of aspirin doses of 75-150 mg/day for secondary cardiovascular prevention, and 50-150 mg/day for secondary cerebrovascular prevention.

NSA — as the leading, independent national nonprofit organization devoting 100 percent of its efforts and resources to stroke — specifically favors the use of low-dose aspirin as a medicinal defender of our country's at-risk population against stroke and its recurrence. In short, our support of McNeil's petition is in alignment with our fundamental reason for being: We are committed to the goal of reducing stroke by 20 percent within this decade by forming alliances with key organizations, institutions and agencies across North America. Through our paired efforts, we can — and will — achieve this critical milestone.

Clinical studies have shown that doses of aspirin in the range of 50-150 mg daily have been demonstrated to be as effective as higher doses for the prevention of serious vascular events, such as nonfatal myocardial infarction, nonfatal stroke or vascular death. Recent studies also have clearly demonstrated that the current recommended daily dose of aspirin in the upper range of 151-325 mg for prevention of serious vascular events, has increased risk for gastrointestinal (GI) bleeding, without providing superior benefit as compared to doses of 50-150 mg. The risk of GI bleeding increases monotonically with increasing aspirin doses and, cardiovascular and cerebrovascular disease benefit is no greater at aspirin doses above 150 mg than below 150 mg/day. Lowering the recommended daily dose of aspirin from 75-325 mg to 75-150 mg for secondary cardiovascular prevention and from 50-325 to 50-150 mg for secondary cerebrovascular prevention, is in keeping with the Food and Drug Administration's Risk Minimization Action Plan and McNeil's long-term goal, to minimize the risk to patients while ensuring beneficial effects.

It seems that the facts match virtually perfectly with the Food and Drug Administration's conclusion a decade ago on this issue; namely, "The positive findings at the lower dosages," along with the higher incidence of side effects expected at the higher dosage (in this case 325 mg daily) "are sufficient reasons to lower the dosage of aspirin for subjects with Transient Ischemic Attacks and stroke." Further, the recommended aspirin dose for chronic administration is 75-150 mg daily, which is safe and effective for prevention of recurrent myocardial infarction, and for treatment of unstable angina pectoris or chronic stable angina pectoris; and 50-150 mg daily for the prevention of ischemic stroke and transient ischemic attacks.

Consequently, the National Stroke Association urges the Food and Drug Administration — as our nation's leading advocate of providing the public with accurate, science-based information for the use of medicines and foods in support of our collective wellness — to approve the Citizen Petition, and to amend the change to the professional labeling for aspirin to change/reduce the recommended maximum daily dose to 150 mg/daily for both secondary cardiovascular prevention, and to 150 mg/daily also for secondary cerebrovascular prevention.

Regards,

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